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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/823,183	03/30/2001	Paul C. Reardon	01801-P0026A	9166

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EXAMINER	
NGUYEN, BAO THUY L	
ART UNIT	PAPER NUMBER
1641	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/823,183	REARDON, PAUL C.	
	Examiner	Art Unit	
	Bao-Thuy L. Nguyen	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2006*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-13,15-25,33-35 and 39-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-13,15-25,33-35 and 39-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 29 June 2006 has been entered.

3. Claims 1-3, 5-13, 15-25, 33-35 and 39-42 are pending.

Claim Rejections - 35 USC § 112, first paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-3, 5-13, 15-25, 33-35 and 39-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims, as amended, recite a method and device for detecting Bence Jones Proteins in *uncentrifuged* urine samples. Such a device and method is not supported by the specification as originally filed. The specification discloses a device and method for detecting Bence Jones Protein in *untreated* human urine samples. No where in the specification is there a disclosure of and *uncentrifuged* urine samples. As such, an *untreated* sample encompasses the instant where buffers, detergents or other assay reagents are not added to the sample prior to the assay; whereas, an *uncentrifuged* sample reads upon a sample that has been *treated* but has not been *centrifuged*.

Applicant is required to cancel the new matter in response to this office action. In the event that Applicant believes that the new matter is supported by the specification as originally filed, Applicant is requested to point to the page and line number in the specification where such support may be found.

6. Claims 1-3, 5-13, 15-25, 33-35 and 39-42 are also not supported by the specification as originally filed because the specification does not disclose a device and method where the chromogenic mobile specific binding partner is added to the urine sample. The specification teaches a device and method comprising a test strip having a substrate pad impregnated with chromogenic mobile specific binding partner and dried thereon. No where in the specification is there a teaching of a device and method where the substrate pad is omitted.

In the event that Applicant believes support for the new matter can be found in the specification, Applicant is requested to point to the page and line number in the specification where such support may be found.

Claim Rejections - 35 USC § 112, second paragraph

7. Claims 1-3, 5-13, 15-25, 33-35 and 39-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 39 are indefinite. The recitation of "said chromatographic mobile specific binding partner" lacks antecedent support.

Claims 1 and 11 are confusing because the use of a label is not recited; therefore, it is unclear how the presence of Bence Jones Protein is determined by viewing the first reaction site. The specification does not teach a method where detection can occur without the use of a label.

Claim 13 is vague with respect to the description of the reagent in the second reaction site. It is unclear if this reagent is *immobilized* in the second reaction site. The reagent is recited as a "second *immobilizing* specific binding agent" that can immobilize a second Bence Jones Protein analyte. If this reagent is not *immobilized* in the second reaction zone, how does it immobilize an analyte?

Claim 15 is indefinite. The recitation of "said first analyte" lacks antecedent support.

Claim 41, "A method" should be changed to -The method-- for clarity.

Claim 41 is also confusing with respect to the location of the chromogenic mobile specific binding partner (herein after labeled binding partner) and the control reaction site. In the instant when the labeled binding partner is located on the test strip, where is it located with respect to the first reaction site and the control site?

The recitation of the second immobilized specific binding reagent in the control site is confusing. Does this reagent bind to the labeled binding partner regardless of whether this labeled binding partner is bound to the analyte?

The step of allowing said uncentrifuged urine to contact said labeled specific binding partner to form an analyte/labeled specific binding partner complex is confusing. In the event that the labeled binding partner is added to the sample (lines 1-2 of claim 41), this allowing step is redundant and confusing. How can you prevent contact between labeled binding partner and the analyte when you add the labeled

binding partner to the sample? In other words, these two separate steps do not make sense if the sample is spiked with labeled reagent.

Claim 41 is further confusing because it is unclear if both, the first reaction site and the control site, contain reagents that bind to a complex comprising the analyte-labeled reagent. If the control site also binds to the complex, how is the analyte detected?

Claim 42, "a device" should be changed to -the device—for clarity.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-3, 5-8, 10-13, 15-21, 23-25 and 39-42 are rejected under 35 USC § 103(a) as being unpatentable over May (GB 2,204,398) in view of Massaro (US 5,141,877).

May teaches an assay device comprising a hollow casing constructed of moisture-impervious solid material. The device contains a dry porous carrier that communicates directly or indirectly with the exterior of the casing. Urine test sample may be applied to the porous carrier. The device containing a labeled specific binding reagent for an analyte that is freely mobile within the porous carrier when in the moist state, and unlabeled specific binding reagent for the same analyte that is permanently

immobilized in a detection zone on the carrier material (page 3). May teaches an embodiment of the invention in which a dry porous nitrocellulose carrier communicates indirectly with the exterior of the casing via a bibulous urine receiving member that protrudes from the casing and can act as a reservoir from which urine is released into the porous carrier (page 7, lines 23-29, see also figure 9 and description on page 23). The device also contains a control zone loaded with an antibody that will bind to the labeled antibody from the first zone. The control zone may also contains an anhydrous reagent that when moistened, produces a color change or color formation. Or as an alternative, the control zone could contain immobilized analyte that will react with excess labeled reagents from the first zone (page 9). May teaches the use of direct labels such as minute colored particles, such as dye sols, metallic sols and colored latex particles (page 10). May teaches a plurality of detection zones arranged in series on the porous solid phase material through which the aqueous liquid sample can pass progressively, can also be used to provide a quantitative measurement of the analyte or can be loaded individually with different specific binding agents to provide a multi-analyte test (page 11). Quantitative measurement may be done visually by eye or by instrument (page 10, lines 10-13). May teaches backing the porous nitrocellulose sheet with plastic to increase handling strength (page 13). May also teaches an absorbant sink provided at the distal end of the carrier material to aid in the flow of sample and to ensure that excess labeled reagent from the first zone which does not participate in any

binding reaction in the second zone is flushed away from the detection zone (page 11; lines 1-17).

May differs from the instant invention in failing to teach the detection of analytes such as free and bound kappa and lambda chains of immunoglobulins.

Massaro, however, teaches the detection of Bence Jones proteins (i.e. free light chains of immunoglobulins) in urine samples. Massaro teaches that the presence of said light chains in the urine is an indication of the existence of a pathological condition (column 1, lines 6-34). Massaro teaches that two types of light chains, kappa and lambda, may be determined from urine (column 2, lines 28-31) using antigen-antibody turbidity reaction methods.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of May to include reagents for the detection of Bence Jones proteins such as taught by Massaro. May teaches that their device may be modified to detect a wide variety of analytes by choice of appropriate specific binding reagents (page 17, lines 4-6) and Massaro teaches that the detection of Bence Jones proteins in the urine is advantageous because it provides a diagnosis of the existence of a pathological condition. A skilled artisan would have had a reasonable expectation of success in using the modified device of May to detect Bence Jones proteins because May teaches that their device provides the advantage of a simple one step device that may be used by an unskilled person giving a result which is rapid and which requires the minimum degree of skilled and involvement from the user (page 1).

10. Claims 9 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over May in view of Massaro as applied to claims 1-3, 5-8, 10-13, 15-21, 23-25 and 39-42 and further in view of Brizgys et al (US 5,807,752).

See the discussion of May and Massaro above. These references differ from the instant invention in failing to teach the use of Protein A.

Brizgys, however, teaches a test system for determining one or more analytes, such as different antibodies isotypes, in a sample (column 3, lines 21-28 and 49-50). Brizgys teaches capture and labeled receptors for the antibodies such as antibodies, antigens and Protein A, etc. (column 4, lines 32-39).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the Protein A taught by Brizgys in the modify device and method of May because Brizgys teaches the Protein A is well known in the art for binding to heavy and light chains of immunoglobulins. The use of protein A also provides the advantages of a universal specific binding reagent for the detection of different isotypes of antibodies.

11. Claims 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over May in view of Massaro as applied to claims 1-3, 5-8, 10-13, 15-21, 23-25 and 39-42 above, and further in view of Deutsch et al (US 4,094,647).

See the discussion of May and Massaro above. These references differ from the instant invention in failing to teach a kit comprising a reaction tube.

Deutsch, however, teaches a similar test device, and in addition, teaches a test tube for holding the test device while the assay progress. Deutsch teaches that the size f the test tube and the dimensions of the test strip may be selected so that the volume of fluid is precisely the amount that is taken up by the test strip. See column 5, lines 46-63.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to assemble the device of May as modified by Massaro, and the test tube of Deutsch into a kit as taught by May. The advantages of assembling various reagents into a kits are well known in the art as providing convenience and economy. Even though the test tube taught by Deutsch is for holding a developing liquid and not a urine sample, it is still deemed to render obvious the instant claims because the intended use of a device is not given patentable weight.

Response to Arguments

12. There were neither amendments to the claims nor any new arguments submitted with the Request for Continued Examination.

13. All arguments filed 07 October 2005 have been fully considered in the response dated 29 December 2005.

Conclusion

14. This is an RCE of applicant's earlier Application No. 09/823,183. All claims are drawn to the same invention claimed in the earlier application and could have been

finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Wednesday from 8:00 a.m. -4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bao-Thuy L. Nguyen
Primary Examiner
Art Unit 1641 12/12/2006